

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

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BARBARA BARTHOLOMEW, TRICIA	:	
BROWN, SHERRY CAMPBELL-DREWERY;	:	
JANET FLECHER, GLORIA GARDNER,	:	
LAUREN GARLAND, PATRICIA	:	
HEDGECOCK, BONNIE MCKELVEY, LULAR	:	
PARKER, JUDY PARSONS, ROBERT RENIX,	:	
LAURA WALTER, CLAUDIA WILLIAMS,	:	
	:	
Plaintiffs,	:	Civil Action
v.	:	No. 04-11188-GAO
	:	
INDEVUS PHARMACEUTICALS, INC., F/K/A	:	
INTERNEURON PHARMACEUTICALS, INC.;	:	<b><u>JURY TRIAL DEMANDED</u></b>
WYETH, INC., F/K/A AMERICAN HOME	:	
PRODUCTS CORPORATION; WYETH	:	
PHARMACEUTICALS, INC F/K/A WYETH-	:	
AYERST PHARMACEUTICALS, INC., A	:	
DIVISION OF AMERICAN HOME PRODUCTS	:	
CORPORATION; AND BOEHRINGER	:	
INGELHEIM PHARMACEUTICALS, INC.,	:	
	:	
Defendants.	:	
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**ANSWER, AFFIRMATIVE DEFENSES AND JURY  
DEMAND OF BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.**

Defendant, Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI"), by its attorneys, and for its Answer to the Complaint, states as follows:

### **INTRODUCTION**

1. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1 of the Complaint, except BIPI specifically denies that Redux<sup>TM</sup> was defective or dangerous and denies that its encapsulation of the chemical compound dexfenfluramine hydrochloride for Indevus Pharmaceuticals, Inc. (f/k/a Interneuron Pharmaceuticals, Inc.) ("Indevus") caused any injuries to Plaintiffs.

### **PARTIES**

2. BIPI denies that Redux caused any injuries to Plaintiffs. BIPI is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 2 of the Complaint.

3. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 3 of the Complaint.

4. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 4 of the Complaint.

5. BIPI denies the allegations in paragraph 5 of the Complaint.

6. BIPI denies the allegations in paragraph 6 of the Complaint.

7. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 7 of the Complaint.

8. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 8 of the Complaint, except that BIPI specifically denies that Redux was defective or dangerous.

9. BIPI denies that Redux is defective or unreasonably dangerous. BIPI denies each and every allegation in paragraph 9 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 9 of the Complaint to the extent they may relate to other defendants.

10. BIPI denies the allegations in paragraph 10 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 10 of the Complaint to the extent they may relate to other defendants. To the extent that the allegations contained in paragraph 10 constitute conclusions of law, no response is required.

11. BIPI denies the allegations in paragraph 11 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 11 of the Complaint to the extent they may relate to other defendants.

### **DEFENDANTS**

12. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 12 of the Complaint except Boehringer admits only, upon information and belief, that Indevus is a corporation having its principal place of business in Lexington, Massachusetts that has at certain times marketed Redux in certain states and that on or about November 21, 1995, BIPI entered into a "Contract Manufacturing Agreement" with Indevus.

13. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 13 of the Complaint.

14. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 14 of the Complaint.

15. BIPI denies the allegations in paragraph 15 of the Complaint as they may relate to BIPI, except it admits only that its principal place of business is 900 Ridgebury Road, Ridgefield, Connecticut 06877; that it encapsulated the chemical compound dexfenfluramine hydrochloride for Indevus; and that on or about November 21, 1995, BIPI entered into a "Contract Manufacturing Agreement" with Indevus. Such agreement speaks for itself and any attempt by Plaintiffs to characterize it is improper and denied. BIPI is without knowledge or information

sufficient to form a belief as to the truth of Plaintiffs' allegations regarding Redux ingestion. To the extent that the allegations contained in paragraph 15 constitute conclusions of law, no response is required.

**FACTUAL ALLEGATIONS**

16. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 16 of the Complaint.

17. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 17 of the Complaint.

18. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 18 of the Complaint.

19. BIPI admits that Aminorex was introduced to the European market in the 1960s. BIPI is without knowledge sufficient to form a belief as to the truth of the remaining allegations of paragraph 19 of the Complaint.

20. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 20 of the Complaint.

21. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 21 of the Complaint.

22. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 22 of the Complaint.

23. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 23 of the Complaint. The research results referenced in paragraph 23 of the Complaint speak for themselves and any attempts by Plaintiffs to characterize them are improper and are denied.

24. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 24 of the Complaint.

25. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 25 of the Complaint.

26. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 26 of the Complaint.

27. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 26 of the Complaint, except it admits that dexfenfluramine was sold in Europe in the 1980s under the names Adifax and Isomeride.

28. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 28 of the Complaint.

29. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 29 of the Complaint.

30. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 30 of the Complaint.

31. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 31 of the Complaint.

32. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 32 of the Complaint.

33. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 33 of the Complaint.

34. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 34 of the Complaint. Dr. Weintraub's articles speak for themselves and any attempts by Plaintiffs to characterize them are improper and are denied.

35. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 35 of the Complaint.

36. BIPI denies the allegation contained in the last sentence of paragraph 36 of the Complaint to the extent that it may relate to BIPI. BIPI is without knowledge or information

sufficient to form a belief as to the truth of the remaining allegations in paragraph 36 of the Complaint.

37. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 37 of the Complaint.

38. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 38 of the Complaint.

39. BIPI denies the allegations of paragraph 39 of the Complaint, including subparts, to the extent that they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the allegations in paragraph 39 of the Complaint to the extent they may relate to other defendants.

40. BIPI denies the allegations of paragraph 40 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 40 of the Complaint to the extent they may relate to other defendants.

41. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 41 of the Complaint. The studies referenced in paragraph 41 speak for themselves and any attempts by Plaintiffs to characterize them are improper and are denied.

42. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 42 of the Complaint.

43. BIPI states that the documents referenced in paragraph 43 of the Complaint speak for themselves and any attempts by Plaintiffs to characterize them are improper and are denied. BIPI denies any remaining allegations of paragraph 43 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 43 of the Complaint to the extent they may relate to other defendants.

44. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 44 of the Complaint.

45. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 45 of the Complaint.

46. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 46 of the Complaint.

47. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 47 of the Complaint.

48. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 48 of the Complaint.

49. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 49 of the Complaint.

50. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 50 of the Complaint.

51. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 51 of the Complaint.

52. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 52 of the Complaint.

53. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 53 of the Complaint.

54. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 54 of the Complaint.

55. BIPI states that the documents referenced in paragraph 55 of the Complaint speak for themselves and any attempts by Plaintiffs to characterize them are improper and are denied. BIPI denies any remaining allegations of paragraph 55 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the

truth of the allegations in paragraph 55 of the Complaint to the extent they may relate to other defendants.

56. BIPI states that the documents and testimony referenced in paragraph 56 of the Complaint speak for themselves and any attempts by Plaintiffs to characterize them are improper and are denied. BIPI denies any remaining allegations of paragraph 56 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 56 of the Complaint to the extent they may relate to other defendants.

57. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 57 of the Complaint.

58. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 58 of the Complaint.

59. To the extent paragraph 59 of the Complaint refers to specific documents, such documents speak for themselves and any attempts by Plaintiffs to characterize them are improper and are denied. BIPI is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 59 of the Complaint.

60. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 60 of the Complaint.

61. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 61 of the Complaint.

62. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 62 of the Complaint.

63. BIPI admits that it entered into a Contract Manufacturing Agreement with Indevus on November 21, 1995. Said document speaks for itself and any attempts by Plaintiffs to characterize it are improper and are denied. BIPI denies any remaining allegations of paragraph 63 of the Complaint.



64. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 64 of the Complaint.

65. BIPI admits the allegations in paragraph 65 of the Complaint.

66. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 66 of the Complaint.

67. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 67 of the Complaint.

68. In response to paragraph 68 of the Complaint, BIPI admits that on or about August 26, 1996, the *New England Journal of Medicine* reported certain results of the International Primary Pulmonary Hypertension Study ("IPPHS"). Said study speaks for itself and any attempts by Plaintiffs to characterize it are improper and are denied.

69. In response to paragraph 69 of the Complaint, BIPI admits that an article appeared in the *New England Journal of Medicine* dated August 29, 1996, entitled "Appetite-suppressant drugs and the risk of primary pulmonary hypertension," that Dr. Stuart Rich was one of the authors of the article and that the article reported the results of the IPPHS. The article speaks for itself and any attempts by Plaintiffs to characterize it are improper and are denied. BIPI denies any remaining allegations of paragraph 69 of the Complaint.

70. BIPI denies the allegations of paragraph 70 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 70 of the Complaint to the extent they may relate to other defendants.

71. BIPI denies the allegations of paragraph 71 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 71 of the Complaint to the extent they may relate to other defendants.

72. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 72 of the Complaint.

73. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 73 of the Complaint.

74. BIPI denies the allegations of paragraph 74 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 74 of the Complaint to the extent they may relate to other defendants.

75. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 75 of the Complaint.

76. BIPI denies the allegations of paragraph 76 of the Complaint to the extent they may relate to BIPI, except it admits only that on or about April 29, 1996, the FDA approved Redux for sale in the United States. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 76 to the extent they may relate to other defendants.

77. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 77 of the Complaint.

78. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 78 of the Complaint.

79. BIPI denies the allegations of paragraph 79 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 79 of the Complaint to the extent they may relate to other defendants.

80. BIPI denies the allegations of paragraph 80 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the

truth of the allegations in paragraph 80 of the Complaint to the extent they may relate to other defendants.

81. BIPI admits that on or about July 8, 1997, the Mayo Clinic issued a press release discussing diet medications. Said press release speaks for itself and any attempts by Plaintiffs to characterize it are improper and are denied. BIPI denies the remaining allegations of paragraph 81 of the Complaint.

82. The documents referenced in paragraph 82 of the Complaint speak for themselves and any attempts by Plaintiffs to characterize them are improper and are denied. BIPI is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 82.

83. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 83 of the Complaint; except it admits that Redux was withdrawn from the market in September, 1997.

84. BIPI admits that the FDA issued a Public Health Advisory on July 8, 1997. The Public Health Advisory speaks for itself and any attempts by Plaintiffs to characterize it are improper and are denied. BIPI is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 86 of the Complaint.

85. The data referenced in paragraph 85 of the Complaint speaks for itself and any attempts by Plaintiffs to characterize it are improper and are denied. BIPI denies the remaining allegations of paragraph 85 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 85 of the Complaint to the extent they may relate to other defendants.

86. The report referenced in paragraph 86 of the Complaint speaks for itself and any attempts by Plaintiffs to characterize it are improper and are denied. BIPI is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 86 of the Complaint.

87. The report referenced in paragraph 86 of the Complaint speaks for itself and any attempts by Plaintiffs to characterize it are improper and are denied. BIPI is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 87 of the Complaint.

88. In response to paragraph 88 of the Complaint, BIPI admits that a report appeared in Morbidity and Mortality Weekly Report dated November 14, 1997, that included recommendations for persons exposed to fenfluramine or dexfenfluramine, developed by the FDA, the National Institutes of Health and the Centers for Disease Control. Said report speaks for itself and any attempts by Plaintiffs to characterize it are improper and are denied.

### **GENERAL ALLEGATIONS**

89. BIPI denies the allegations of paragraph 89 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 89 of the Complaint to the extent they may relate to other defendants.

90. BIPI denies the allegations of paragraph 90 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 90 of the Complaint to the extent they may relate to other defendants.

91. BIPI denies the allegations of paragraph 91 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 91 of the Complaint to the extent they may relate to other defendants.

92. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 92 of the Complaint.

93. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 93 of the Complaint.

94. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 94 of the Complaint.

95. BIPI denies the allegations of paragraph 95 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 95 of the Complaint to the extent they may relate to other defendants.

96. BIPI denies the allegations of paragraph 96 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 96 of the Complaint to the extent they may relate to other defendants.

97. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 97 of the Complaint.

98. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 98 of the Complaint.

99. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 99 of the Complaint.

100. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 100 of the Complaint.

101. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 101 of the Complaint.

102. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 102 of the Complaint.

103. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 103 of the Complaint.

104. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 104 of the Complaint.

105. BIPI denies the allegations of paragraph 105 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 105 of the Complaint to the extent they may relate to other defendants.

106. BIPI denies the allegations of paragraph 106 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 106 of the Complaint to the extent they may relate to other defendants.

107. BIPI denies the allegations of paragraph 107 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 107 of the Complaint to the extent they may relate to other defendants.

108. BIPI denies the allegations of paragraph 108 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 108 of the Complaint to the extent they may relate to other defendants. To the extent that the allegations in paragraph 108 of the Complaint constitute conclusions of law, no response is required.

109. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 109 of the Complaint.

110. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 110 of the Complaint.

111. BIPI denies the allegations of paragraph 111 of the Complaint.

112. BIPI denies the allegations of paragraph 112 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 112 of the Complaint to the extent they may relate to other defendants.

113. BIPI denies the allegations of paragraph 113 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 113 of the Complaint to the extent they may relate to other defendants.

114. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in the last sentence of paragraph 114 of the Complaint. BIPI denies the remaining allegations of paragraph 114 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 114 of the Complaint to the extent they may relate to other defendants.

115. BIPI denies the allegations of paragraph 115 of the Complaint.

116. BIPI denies the allegations of paragraph 116 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 116 of the Complaint to the extent it may relate to other defendants.

117. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 117 of the Complaint.

**COUNT I**  
**STRICT PRODUCT LIABILITY – DEFECTIVE DESIGN**

118. In response to paragraph 118 of the Complaint, BIPI restates its answers to the preceding paragraphs of the Complaint with the same force and legal effect as if fully set out herein.

119. BIPI denies the allegations of paragraph 119 of the Complaint to the extent they may relate to BIPI and denies that Redux was defective or unreasonably dangerous. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 119 of the Complaint to the extent they may relate to other defendants.

120. BIPI denies the allegations of paragraph 120 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the

truth of the allegations in paragraph 120 of the Complaint to the extent they may relate to other defendants.

121. BIPI denies the allegations of paragraph 121 of the Complaint, including subparts, to the extent they may relate to BIPI and denies that Redux was defective or unreasonably dangerous. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 121 of the Complaint to the extent they may relate to other defendants.

122. BIPI denies the allegations of paragraph 122 of the Complaint.

123. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 123 of the Complaint purporting to describe Plaintiffs' injuries, but denies that such injuries were causally related to Redux, denies that Redux was in a defective condition and otherwise denies the allegations of paragraph 123.

Plaintiffs' WHEREFORE clause and prayer for relief are denied.

**COUNT II**  
**STRICT PRODUCT LIABILITY – FAILURE TO WARN**

124. In response to paragraph 124 of the Complaint, BIPI restates its answers to the preceding paragraphs of the Complaint with the same force and legal effect as if fully set out herein.

125. BIPI denies the allegations of paragraph 125 of the Complaint to the extent they may relate to BIPI and denies that Redux was defective or unreasonably dangerous. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 125 of the Complaint to the extent it may relate to other defendants.

126. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 126 of the Complaint.

127. BIPI denies the allegations of paragraph 127 of the Complaint.

128. The allegation contained in paragraph 128 of the Complaint constitutes a conclusion of law, to which no response is required.



129. BIPI denies the allegations of paragraph 129 of the Complaint to the extent they relate to Redux. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 129 to the extent they relate to Pondimin.

130. BIPI denies the allegations of paragraph 130 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 130 of the Complaint to the extent they may relate to other defendants.

131. BIPI denies the allegations of paragraph 131 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 131 of the Complaint to the extent they may relate to other defendants.

132. BIPI denies the allegations of paragraph 132 of the Complaint to the extent that they may relate to BIPI, except it admits only to any duties imposed by law. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 132 of the Complaint to the extent they may relate to other defendants. To the extent the allegations in paragraph 132 constitute conclusions of law, no response is required.

133. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 133 of the Complaint purporting to describe Plaintiffs' injuries, but denies that such injuries were causally related to Redux, denies Plaintiffs' failure to warn allegations and otherwise denies the allegations of paragraph 133 to the extent that they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 133 of the Complaint to the extent they may relate to other defendants.

Plaintiffs' WHEREFORE clause and prayer for relief are denied.

**COUNT III**  
**NEGLIGENCE**

134. In response to paragraph 134 of the Complaint, BIPI restates its answers to the preceding paragraphs of the Complaint with the same force and legal effect as if fully set out herein.

135. BIPI denies the allegations of paragraph 135 of the Complaint to the extent they may relate to BIPI, except BIPI admits only that it encapsulated the chemical compound dexfenfluramine hydrochloride for Indevus. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 135 of the Complaint to the extent they may relate to other defendants.

136. BIPI denies the allegations of paragraph 136 of the Complaint to the extent they may relate to BIPI, except it admits only to any duties imposed by law. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 136 of the Complaint to the extent they may relate to other defendants. To the extent the allegations in paragraph 136 constitute conclusions of law, no response is required.

137. BIPI denies the allegations of paragraph 137 of the Complaint, including subparts, to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 137 of the Complaint, including subparts, to the extent they may relate to other defendants.

138. BIPI denies the allegations of paragraph 138 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 138 of the Complaint to the extent they may relate to other defendants.

139. BIPI denies the allegations of paragraph 139 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 139 of the Complaint to the extent they may relate to other defendants.

140. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 140 of the Complaint purporting to describe Plaintiffs' injuries, but denies that such injuries were causally related to Redux and otherwise denies the allegations of paragraph 140 to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 140 of the Complaint to the extent they may relate to other defendants.

Plaintiffs' WHEREFORE clause and prayer for relief are denied.

**COUNT IV**  
**FRAUDULENT MISREPRESENTATION**

141. In response to paragraph 141 of the Complaint, BIPI restates its answers to the preceding paragraphs of the Complaint with the same force and legal effect as if fully set out herein.

142. BIPI denies the allegations of paragraph 142 of the Complaint to the extent they may relate to BIPI, except BIPI admits only that it encapsulated the chemical compound dexfenfluramine hydrochloride for Indevus. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 142 of the Complaint to the extent they may relate to other defendants.

143. BIPI denies the allegations of paragraph 143 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 143 of the Complaint to the extent they may relate to other defendants.

144. BIPI denies the allegations of paragraph 144 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 144 of the Complaint to the extent they may relate to other defendants.

145. BIPI denies the allegations of paragraph 145 of the Complaint.

146. BIPI denies the allegations of paragraph 146 of the Complaint, including subparts, to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 146 of the Complaint, including subparts, to the extent they may relate to other defendants.

147. BIPI denies the allegations of paragraph 147 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 147 of the Complaint to the extent they may relate to other defendants.

148. BIPI denies the allegations of paragraph 148 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 148 of the Complaint to the extent they may relate to other defendants.

149. BIPI denies the allegations of paragraph 149 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 149 of the Complaint to the extent they may relate to other defendants.

150. BIPI denies the allegations of paragraph 150 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 150 of the Complaint to the extent they may relate to other defendants.

151. BIPI denies making any false and/or misleading representations. BIPI is without knowledge or information sufficient to form a belief concerning the remaining allegations of paragraph 151 of the Complaint, and therefore denies said allegations.

152. BIPI denies the allegations of paragraph 152 of the Complaint to the extent they may relate to BIPI, except BIPI admits only to any duties imposed by law. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in

paragraph 152 to the extent they may relate to other defendants. To the extent the allegations in paragraph 152 constitute conclusions of law, no response is required.

153. BIPI denies the allegations of paragraph 153 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 153 to the extent they may relate to other defendants. To the extent the allegations in paragraph 153 constitute conclusions of law, no response is required.

154. BIPI denies the allegations of paragraph 154 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 154 to the extent they may relate to other defendants.

155. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 155 of the Complaint, to the extent they may relate to BIPI, purporting to describe Plaintiffs' injuries, but denies that such injuries were causally related to Redux, denies Plaintiffs' misrepresentation and fraudulent concealment allegations and otherwise denies the allegations of paragraph 155. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 155 to the extent they may relate to other defendants.

Plaintiffs' WHEREFORE clause and prayer for relief are denied.

**COUNT V**  
**FRAUDULENT CONCEALMENT**  
**(AGAINST DEFENDANT INDEVUS ONLY)**

156-170. Count V of the Complaint is not asserted against BIPI and, therefore, no answer is required from this defendant. To the extent that the allegations of Count V may be construed to relate to BIPI, they are denied.

**COUNT VI**  
**G.L. c. 93A UNFAIR AND DECEPTIVE PRACTICES**  
**(AGAINST DEFENDANTS INDEVUS AND BOEHRINGER ONLY)**

171. In response to paragraph 171 of the Complaint, BIPI restates its answers to the preceding paragraphs of the Complaint with the same force and legal effect as if fully set out herein.

172. BIPI denies the allegations of paragraph 172 of the Complaint to the extent they relate to BIPI, except it admits only that it performed the service function of encapsulating the chemical compound dexfenfluramine hydrochloride for Indevus pursuant to Indevus' specific contractual specifications as more fully set forth in the Contract Manufacturing Agreement entered into between Boehringer and Indevus. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 172 to the extent they relate to other defendants. To the extent that the allegations contained in paragraph 172 constitute conclusions of law, no response is required.

173. BIPI denies the allegations of paragraph 173 of the Complaint to the extent they relate to BIPI, except it admits only that it performed the service function of encapsulating the chemical compound dexfenfluramine hydrochloride for Indevus pursuant to Indevus' specific contractual specifications as more fully set forth in the Contract Manufacturing Agreement entered into between Boehringer and Indevus. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 173 to the extent they relate to other defendants. To the extent that the allegations contained in paragraph 173 constitute conclusions of law, no response is required.

174. BIPI denies the allegations of paragraph 174 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 174 to the extent they may relate to other defendants.

175. BIPI denies the allegations of paragraph 175 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 175 to the extent they may relate to other defendants.

176. BIPI denies the allegations of paragraph 176 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 176 to the extent they may relate to other defendants.

177. BIPI denies the allegations of paragraph 177 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 177 to the extent they may relate to other defendants.

178. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations regarding what Plaintiffs relied upon in paragraph 178 of the Complaint and denies the remaining allegations of paragraph 178 to the extent that they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 178 to the extent they may relate to other defendants.

179. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 179 of the Complaint purporting to describe Plaintiffs' injuries, but denies that such injuries were causally related to Redux, denies Plaintiffs' allegations of unfair and deceptive acts or practices and otherwise denies the allegations of paragraph 179 to the extent that they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 179 to the extent they may relate to other defendants.

180. BIPI denies the allegations of paragraph 180 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 180 to the extent they may relate to other defendants.

181. BIPI denies the allegations of paragraph 181 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 181 to the extent they may relate to other defendants.

182. BIPI denies the allegations of paragraph 182 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 182 to the extent they may relate to other defendants.

183. BIPI denies the allegations of paragraph 183 of the Complaint to the extent they may relate to BIPI. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 183 to the extent they may relate to other defendants.

184. BIPI denies the allegations in paragraph 184 of the Complaint.

Plaintiffs' WHEREFORE clause and prayer for relief are denied.

### **GENERAL DENIAL**

BIPI denies each and every allegation contained in the Complaint that is not specifically admitted to be true.

### **AFFIRMATIVE DEFENSES**

FIRST. The Complaint and each claim contained therein fails to state a claim upon which relief can be granted against Boehringer, which responsibility is denied, because the duties that plaintiffs claim were breached by all of the "Defendants" are not, as a matter of law, imposed upon a party such as Boehringer, which did not sell, distribute or market dexfenfluramine hydrochloride, but merely received a chemical compound (here dexfenfluramine) through another defendant and/or company and, pursuant to the co-defendant's and/or company's detailed contractual specifications and applicable government (FDA) regulations and guidelines, assembled the compound into capsule dosage forms of a drug, added associated packaging, the product label and labeling provided by another co-defendant an/or another company and provided the same (again, pursuant to express contractual specifications) to the co-defendant -- not to the plaintiffs or any other members of the public.

SECOND. The Complaint and each claim contained therein fails to state a claim upon which relief can be granted against Boehringer, because Boehringer has not performed or conducted any non-clinical or clinical research (including but not limited to medicinal chemistry



or other similar basic chemical research) regarding dexfenfluramine hydrochloride. Boehringer had no role in the pre-clinical development of dexfenfluramine hydrochloride, including the formulation, pharmacology, toxicology and kinetics, or clinical research relating to scale-up formulation or Phases I-III of the clinical trials. Furthermore, Boehringer had no direct or indirect interactions with the FDA concerning Indevus' IND and NDA submissions, meetings or any other similar contacts and was not involved in any way with the development of the labeling language or the promotion, safety monitoring, Phase IV post-marketing surveillance or any other similar regulatory obligation in connection with Redux™.

THIRD. Plaintiffs' claims are barred, reduced and/or limited pursuant to applicable statutory and common law regarding limitations of awards, caps on recovery, and setoffs.

FOURTH. If plaintiffs have sustained any injuries or incurred any expenses, such were not caused by Boehringer, but were caused in whole or in part by the acts or omissions of others, whether individual, corporate or otherwise, whether named or unnamed in the Complaint, and for whose conduct Boehringer is not responsible.

FIFTH. If plaintiffs have sustained any injuries or damages, such were the result of intervening or superseding events, factors, occurrences or conditions, which were in no way caused by Boehringer and for which Boehringer is not liable.

SIXTH. Plaintiffs may not recover from Boehringer because the methods, standards, or techniques of encapsulating and labeling Indevus' products complied with and were in conformity with the generally recognized state of the art, and applicable government (FDA) regulations, standards and guidelines, at the time the product was designed, manufactured, and labeled.

SEVENTH. Plaintiffs' claims, if any, are barred, in whole or in part, by the applicable statutes of limitations and of repose.

EIGHTH. Plaintiffs' claims, if any, are barred, in whole or in part, by the doctrines of laches, waiver, estoppel and/or ratification.

NINTH. To the extent plaintiffs' claims relate to Boehringer's advertising, public statements, lobbying, or other activities, if any, protected by the First Amendment to the Constitution of the United States and by applicable State Constitutions, such claims are barred.

TENTH. Plaintiffs' claims are barred, in whole or in part, by their failure to mitigate any damages allegedly sustained.

ELEVENTH. Plaintiffs' claims are barred by their alteration, modification, abuse, and/or misuse of the product or products at issue.

TWELFTH. Plaintiffs' claims are preempted, in whole or in part, by federal laws and regulations, including (without limitation) those governing the labeling, advertisement and sale of pharmaceutical products.

THIRTEENTH. Plaintiffs' claims are barred or reduced by their contributory and/or comparative negligence, and/or contributory and/or comparative fault.

FOURTEENTH. Plaintiffs' damages, if any, were the direct result of their pre-existing medical conditions, and/or occurred by operation of nature or as a result of circumstances over which Boehringer had and continues to have no control.

FIFTEENTH. This Court lacks personal jurisdiction over Boehringer.

SIXTEENTH. Plaintiffs' claims are barred by plaintiffs' assumption of risk.

SEVENTEENTH. Boehringer is not subject to liability under Restatement (Second) of Torts § 402A, comment k.

EIGHTEENTH. Boehringer is not subject to liability under Restatement (Third) of Torts: Products Liability, § 6.

NINETEENTH. Any verdict or judgment that might be recovered by plaintiffs must be reduced by those amounts that have already or will in the future have, with reasonable certainty, indemnify plaintiffs in whole or in part for any past or future claimed economic loss from any collateral source such as insurance, social security, worker's compensation, or employee benefit program.

TWENTIETH. The benefits of the products at issue outweigh the risks, if any, alleged in plaintiffs' Complaint.

TWENTY-FIRST. Plaintiffs' claims are barred by the intervention of a learned intermediary whose omissions, acts, or fault are the cause of plaintiffs' damages, if any.

TWENTY-SECOND. Plaintiffs' claims are barred because of plaintiffs' failure to join necessary and indispensable parties.

TWENTY-THIRD. The Complaint fails to allege a claim for which punitive or exemplary damages can be recovered.

TWENTY-FOURTH. Plaintiffs' claims for punitive or exemplary damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, the Full Faith and Credit Clause of the United States Constitution and applicable provisions of the relevant state constitutions.

TWENTY-FIFTH. Plaintiffs have failed to state their fraud claim with sufficient particularity.

TWENTY-SIXTH. Boehringer adopts and incorporates by reference any affirmative defense asserted by any other defendant to this action, to the extent such affirmative defense applies to Boehringer.

#### **DEFENSES RESERVED**

BIPI hereby gives notice that it intends to rely upon any other defenses that may become available or apparent during the discovery proceedings in this matter and hereby reserves its right to amend its Answer and to assert any such defense.

#### **DEMAND FOR BIFURCATED TRIAL**

If Plaintiffs are allowed to proceed to trial upon any claims for punitive or exemplary or exemplary damages, such claims, if any, must be bifurcated from the other issues.

**DEMAND FOR JURY TRIAL**

BIPI demands a jury trial as to all issues so triable in this action.

WHEREFORE, Defendant BIPI respectfully requests that this Court:

- (a) Grant BIPI judgment on all of Plaintiffs' claims and dismiss the Complaint with prejudice;
- (b) Award BIPI its costs and attorneys' fees for defense of the Complaint;
- (c) Award BIPI such other relief as the Court deems just and proper.

Dated: June 23, 2004  
Boston, Massachusetts

Respectfully submitted,

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